K080217

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510(k) Summary

NOV - 5 2008

Submitter: Moberg Research, Inc.
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Ambler, PA 19002
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Contact Person: Damon Lees

Device Trade Name: Component Neuromonitoring System™

Common Name: EEG Monitor

Classification Name: Electroencephalograph (21CFR882.1400, Product Code: GWQ)

Date of Preparation: September 22, 2008

Substantially Equivalent Devices:

Product Name	*510(k) Number*	*Manufacturer / Submitter*
A-2000 EEG Monitor with BIS	k974496	Aspect Medical
Bravo Multi-Modality System	k991054	Nicolet Biomedical
BRM2 Brain Monitor	K033010	BrainZ Instruments
CFM 6000	k031149	Olympic Medical
HARMONIE-Schwarzer EEG System	k010728	Stellate Systems
Integra Mobius Multi-Modality System	k061640	Integra NeuroSciences
Nervus Monitor	k021185	Taugagreining HF
Neurotrac II-EP	k960170	Moberg Medical
Lectromed Cerebral Function Monitor System	k983229	Olympic Medical

Indications for Use:

The Component Neuromonitoring System™ is intended to monitor the state of the brain by recording and displaying EEG signals, and can also receive and display a variety of vital signs and other measurements from third-party monitoring devices (such as ICP, ECG, SpO_2, and others). It also has the optional capability to record and display patient video.

The Component Neuromonitoring System is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment, including the operating room, intensive care unit, emergency room, and clinical research settings.

Device Description:

The Component Neuromonitoring System (CNS) is a portable, computer based system that can continuously record, display, store, and analyze physiological data from multiple monitoring sources

in real-time. Electroencephalographic (EEG) data can be recorded from up to 16 electrode locations using the included EEG amplifier. Video can be recorded using an optional video camera. Other data can be recorded from interfaces to third-party monitoring devices, or can be manually entered.

The CNS Monitor consists of the following main physical components: a color flat-panel touch-screen display, an integrated computer system, a Device Interface Module, and an EEG Amplifier. All hardware components of the monitor are mounted on a wheeled pole stand to provide a compact design, convenient use, and ease of transportation. An Ethernet port is located at the base of the system to allow the archival of patient data to a network. A storage basket can hold electrode supplies, and can also hold the EEG amplifier when the system is not in use.

The *Device Interface Module* contains six digital serial interfaces for connecting to external monitoring devices and four MDport™ (USB) interfaces used for connecting to other CNS components (such as the EEG Amplifier) or to electrically isolated, USB-based, external monitoring devices. The Device Interface Module also contains a CD/DVD drive for archiving patient recordings, for updating the system software, and for other data storage or retrieval purposes.

The *EEG Amplifier* is small and lightweight and connects to the Device Interface Module with a flexible 15' cord. It has 19 inputs (including Reference, Ground, and auxiliary inputs) and can record from up to 16 EEG electrode sites. Up to 6 inputs can be used as differential pairs for other physiological signals (e.g.: ECG, EOG, respiration, etc.). Continuous impedance checking automatically detects any electrodes that become loose or detached.

Data can be viewed on the CNS Monitor using a variety of display types: waveform, trend, numeric readout, compressed spectral array (CSA), and density spectral array (DSA). Combinations of multiple display types can be configured in a variety of screen layouts to allow the comparison of different measurements or different time periods from the recording.

The CNS Monitor can compute processed parameters from the EEG data, including: Amplitude Integrated EEG (aEEG), Total Power, Spectral Edge Frequency, EEG Band Power Percentages (delta, theta, alpha, beta), Envelope Amplitude, % Asymmetry, % Suppression, and Inter-Burst Interval (IBI).

The CNS Monitor also has several features to enable ease-of-use. It employs monitoring protocols that can step the user through a monitoring procedure and configure a group of settings for the recording (including EEG electrode sites & montage, collected measurements, and display settings). Pre-configured protocols are included on the system and the user can also create their own customized protocols. Embedded reference content can be viewed on the CNS Monitor to assist the user with system features, device connections, electrode application, and other topics.

Comparison of Technological Characteristics to Predicate Devices:

The Component Neuromonitoring System has the combined technological characteristics of the specified predicate devices. The system can record and display both digital EEG and video, compute various processed parameters from the EEG, and digitally interface to third-party monitoring devices for the collection and storage of other measurements.

Summary of Performance Testing:

The Component Neuromonitoring System has undergone validation and verification testing to ensure conformance to all design requirements. Additionally, the system has undergone comparison testing to ensure the substantial equivalence of the calculation and display of the aEEG.

To ensure safety, the Component Neuromonitoring System will comply with all applicable requirements of IEC60601-1 and IEC60601-1-4, and will also comply with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

To ensure electromagnetic compatibility, the Component Neuromonitoring System will comply with all applicable requirements of IEC60601-1-2, and will also comply with the particular requirements for the safety of electroencephalographs established in IEC60601-2-26.

Conclusion of Substantial Equivalence:

The comparison of technological characteristics and performance testing of the Component Neuromonitoring System demonstrate that its safety, effectiveness, and performance are equivalent to the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Moberg Research, Inc.
c/o CITECH
Mr. Robert Mosenkis
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

APR - 9 2012

Re: K080217
Trade/Device Name: Component Neuromonitoring System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMA, GWQ, OLT, MUD, MHX, ORT
Dated (Date on orig SE ltr): October 20, 2008
Received (Date on orig SE ltr): October 21, 2008

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of November 5, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if known):

Device Name: Component Neuromonitoring System

Indications For Use:

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Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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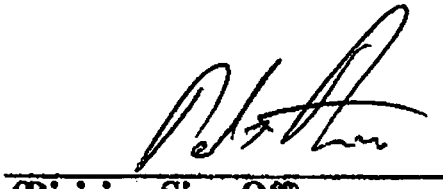
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices 11/4/04

510(k) Number K050217